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DRINKER BIDDLE & REATH LLP
A Delaware Limited Liability Partnership
500 Campus Drive
Florham Park, New Jersey 07932-1047
(973) 549-7000
Attorneys for Defendants,
JOHNSON & JOHNSON, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C., and ORTHO-McNEIL PHARMACEUTICAL, INC., now known as ORTHO-McNEIL-JANSSEN PHARMACEUTICALS, INC.

VICKI SEALS AND KEVIN SEALS, W/H, Plaintiffs, v. ORTHO-McNEIL PHARMACEUTICAL, INC., JOHNSON & JOHNSON, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, L.L.C. f/k/a R.W. JOHNSON PHARMACEUTICAL RESEARCH INSTITUTE, JANE DOE DISTRIBUTORS (1-50), JILL DOE MANUFACTURERS (1-50), JACK DOE WHOLESALERS (1-50), JAKE DOE SELLERS (1-50), JOHN DOE MARKETERS (1-50), JOAN DOE FORMULATORS (1-50), JIM DOE HEALTH CARE PROVIDERS (1-50), and JEAN DOE (1-50), Defendants.	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: MIDDLESEX COUNTY DOCKET NUMBER MID-L-9861-08-MT CIVIL ACTION IN RE ORTHO EVRA® BIRTH CONTROL PATCH LITIGATION CASE CODE 275 **ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AS TO PLAINTIFFS' FAILURE TO WARN CLAIMS**

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for Defendants Johnson & Johnson, Johnson & Johnson Pharmaceutical Research & Development, L.L.C., and Ortho-McNeil Pharmaceutical, Inc., now known as Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Defendants"), on Motion for Summary Judgment as to Plaintiffs'

Failure to Warn Claims; and the Court having considered the papers submitted; ~~and the Court having heard the arguments of counsel, if any~~, and for good cause shown;

IT IS ON THIS 16th **day of** August **, 2010;**

ORDERED as follows

(1) Defendants' Motion for Summary Judgment as to Plaintiffs' Failure to Warn Claims is hereby GRANTED. DENIED *

(2) A signed copy of this Order be ~~served on~~ posted by all counsel within 7 days of the date hereof.

Hon. Jessica R. Mayer, J.S.C.

____ Unopposed

✓ Opposed

* For the reasons set forth in the court's memorandum dated August 6, 2010.

OPPOSED

SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.

MIDDLESEX COUNTY COURT HOUSE
P.O. Box 964
NEW BRUNSWICK, NEW JERSEY 08903-0964

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

Memorandum of Decision on Defendants' Motion for Summary Judgment

Seals v. Ortho-McNeil Pharmaceutical, Inc., et al.
Docket No. MID-L-9861-08-MT

Defendants: Susan Sharko, Esq., Drinker Biddle & Reath LLP

Plaintiff: Kevin Haverty, Esq., Williams Cuker Berezofsky LLC

Dated: August 6, 2010

Background

Plaintiffs Vicki and Kevin Seals (collectively, "Plaintiffs") filed an amended complaint on November 25, 2008 asserting multiple causes of action against Defendants Ortho-McNeil-Janssen Pharmaceuticals, Inc., Johnson & Johnson, and Johnson & Johnson Research & Development, L.L.C ("Defendants") for damages allegedly caused by use of Ortho-Evra®, a prescription birth control patch that releases estrogen transdermally. On June 11, 2110, Defendants moved for partial summary judgment on Plaintiffs' failure-to-warn claim. Plaintiffs filed opposition on July 27, 2010. Defendants filed a reply on August 2, 2010. Counsel agreed to waive oral argument and consented to the court's disposition of this motion on the papers submitted.

Statement of Material Facts

Ms. Seals, an Ohio citizen, began using Ortho-Evra® in September 2003 after consulting with her prescribing physician, Dr. Ronald Lopez ("Dr. Lopez"). Ms. Seals continued to use Ortho-Evra® until September 2005, when she discontinued the patch for financial reasons. In February 2006, Ms. Seals returned to Dr. Lopez seeking another prescription for Orth-Evra® to help regulate her menstrual cycle and improve her polycystic ovarian syndrome. Prior to February 2006, Dr. Lopez had received information on additional risks associated with Ortho-Evra®, including the risk of blood clot and stroke. In February 2006, after discussing with Ms. Seals the potential adverse events, including the risk of stroke, Dr. Lopez continued Ms. Seals's prescription of Ortho-Evra®. In September 2006, Dr. Lopez prescribed continuous use of Ortho-Evra® to treat Ms. Seals's uterine bleeding, endometriosis, and fibroid tumors. Ms. Seals was advised by Dr. Lopez to use the patch continuously for three months without taking the one week off as recommended per the Ortho-Evra® label. In February 2007, Ms. Seals was admitted to the hospital and diagnosed with a pulmonary embolism and deep vein thrombosis ("DVT").

Defendants' Motion

Defendants argue that Plaintiffs' failure-to-warn claim fails because Defendants adequately warned Ms. Seals's prescribing physician of the risks associated with Ortho-Evra® consistent with the Ohio Product Liability Act ("OPLA"). Defendants assert that the label for Ortho-Evra® fully disclosed the risks of pulmonary embolism associated with the use of the birth control patch. Defendants argue that Dr. Lopez, who prescribed Ortho-Evra® to Ms. Seals, was fully informed and aware of the potential side effects and specifically discussed the risks with Ms. Seals. Dr. Lopez still prescribes Ortho-Evra® to patients who choose the patch as a

birth control option. As a result, Defendants request summary judgment as a matter of Ohio law.

Additionally, Defendants argue that even if Plaintiffs were to establish a failure-to-warn claim, any damages are subject to the limitations on noneconomic damages under Ohio law. Defendants claim that Ms. Seals's alleged injuries are not "catastrophic" so as to be exempt from the cap under Ohio law. Thus, Defendants contend that Plaintiffs' recovery of noneconomic damages is limited by Ohio law.

Plaintiffs' Opposition

Plaintiffs dispute that the learned intermediary doctrine warrants summary judgment as to Plaintiffs' failure-to-warn claim.[1] Specifically, Plaintiffs challenge the applicability of the learned intermediary doctrine under Ohio law and New Jersey law. Plaintiffs also maintain that New Jersey law governs Plaintiffs' damage claims.

Plaintiffs argue that summary judgment must be denied under New Jersey law. Plaintiffs contend that New Jersey's learned intermediary doctrine does not apply to certain types of drugs. Plaintiffs claim that there is an exemption to the doctrine where the United States Food and Drug Administration ("FDA") requires direct communication of risks of drugs to the patient by the physician. Plaintiffs rely on a federal district court case upholding an FDA decision requiring doctors to warn patients directly about the risk of estrogen-containing birth control medication. See Pharmaceutical Mfrs. Ass'n v. Food & Drug Admin., 484 F. Supp. 1179 (D. Del 1980). Plaintiffs contend that this court should adopt the federal court's reasoning and conclude that all estrogen-containing birth control, including Ortho-Evra®, is exempt from the learned intermediary doctrine.

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[1] The learned intermediary doctrine requires a drug manufacturer to warn the prescribing health care professional and serves as an exception to a manufacturer's duty to warn the consumer. See Niemiera v. Schneider, 114 N.J. 550, 559 (1989); Seley v. G.D. Searle & Co., 67 Ohio St.2d 192 (Ohio 1981).

Plaintiffs also argue that the learned intermediary doctrine does not apply where the manufacturer marketed its product directly to consumers. Plaintiffs posit that Defendants directly marketed Ortho-Evra® to consumers and, therefore, cannot invoke the learned intermediary doctrine.

Next, Plaintiffs argue that the learned intermediary doctrine does not apply under Ohio law. Plaintiffs claim that the Ohio Supreme Court's application of the learned intermediary doctrine to contraceptives occurred prior to the FDA's mandating of direct warnings to consumers regarding the risks of estrogen containing drug products. See 21 C.F.R. § 310.515 (2010); Seley, supra, 67 Ohio St.2d at 202 n.6. Plaintiffs note a recent Ohio court's decision discussing an exception for "contraceptive medications and devices, where the patient is actively involved in the decision and the products are used for extended periods of time without medical assessment." Kennedy v. Merck & Co., 2003 Ohio App. LEXIS 3388 (Ohio Ct. App., 2d Dist., Montgomery County, July 3, 2003), Slip. op. at 13. Plaintiffs claim that Ortho-Evra® falls within the exception identified in Kennedy and, therefore, Defendants are not entitled to the learned intermediary doctrine.

Finally, Plaintiffs challenge Defendants' position that Ohio law is applicable in this case. Plaintiffs argue Defendants waived the right to claim application of Ohio law. Plaintiffs further argue that there is no conflict as to the unavailability of the learned intermediary doctrine defense under either New Jersey law or Ohio law and, therefore, this court need not render a choice-of-law determination. Finally, Plaintiffs claim that even if a conflict does exist between the States' laws, New Jersey law applies. Therefore, Plaintiffs conclude that summary judgment must be denied.

Defendants' Reply

Defendants argue that choice-of-law was not waived and that Ohio law governs Plaintiffs' claims. Furthermore, Defendants assert that Plaintiffs misstate Ohio law regarding the learned intermediary doctrine as Seley was not abrogated by Ohio Rev. Code Ann. § 2307.76(C). Defendants also claim that even if New Jersey law applies in this case, Plaintiffs' failure-to-warn claim fails under the learned intermediary doctrine. Defendants also note the absence of any evidence that Ms. Seals viewed direct-to-consumer advertisements so as to negate the learned intermediary doctrine defense.

Legal Analysis

Prior to the filing of this motion, the court erroneously presumed that the parties agreed as to which State's law governed the substantive claims in this matter. In prior case management conferences with the court, counsel discussed choice-of-law with respect to one of the bellwether cases in this litigation.[2] Counsel in Herring apparently stipulated that California law applied to the plaintiff's claim for compensatory damages and to liability issues, but reserved the right to file a choice-of-law motion as to which State's law governed the plaintiff's claim for punitive damages. Based on the Herring case, the court mistakenly assumed that all cases pending in the In Re: Ortho-Evra Birth® Control Patch Litigation, Case No. 275, had similar stipulations governing choice-of-law as to substantive claims and compensatory damages but left the issue of choice-of-law for punitive damage claims to be resolved at a later date, prior to trial. It was not until the court read Plaintiffs' opposition brief and Defendants' reply brief for this motion that the court realized it had made a mistake in presuming that counsel for each of the cases pending

[2] That bellwether case was Herring v. Ortho-McNeil-Janssen Pharmaceuticals, Inc. et. at., Docket No. L-5787-07 ("Herring").

in this mass tort litigation agreed to apply the substantive and compensatory damages laws of the state where the plaintiff resided/used the birth control patch. Based upon the papers submitted for this motion, the court belatedly realized that its presumption as to resolution of choice-of-law was incorrect. The court apologizes to counsel for the court's mistaken belief that choice-of-law for Plaintiffs' substantive claims and compensatory damages was resolved by counsel without need for judicial resolution prior to the filing of this dispositive motion.

In their moving papers, Defendants summarily stated that Ohio law governed Plaintiffs' case. This perpetuated the court's flawed belief that choice-of-law as to all issues except punitive damages had been resolved. In opposition, Plaintiffs argued that New Jersey law was to be applied to all claims. In their reply, Defendants revealed that Plaintiffs' counsel did not respond to efforts by defense counsel to reach an agreement on the choice-of-law issue. Defendants maintained that Ohio law should apply.

Due to the court's erroneous belief that choice-of-law for substantive claims had been resolved by counsel, the court permitted Defendants to file a dispositive motion as to Plaintiffs' failure-to-warn claim. It is now clear to the court that the choice-of-law issue remains undecided in this case. This court must first determine the applicable law governing Plaintiffs' substantive claims prior to determining whether summary judgment is warranted. Only one State's law can apply to the substantive claims in this case. For the court to analyze this case under the laws of both Ohio and New Jersey would essentially amount to the court providing an advisory opinion. A court should decline to answer abstract questions or give advisory opinions. See G.H. v. Township of Galloway, 199 N.J. 135, 136 (2009). The choice-of-law conflict in this case must be resolved prior to the court rendering a determination as to summary judgment. As such, the

court denies Defendants' motion for summary judgment without prejudice. Defendants may renew their motion for summary judgment after the choice-of-law question is resolved.

As a separate point, the court notes that both parties failed to file a separate statement of material facts as required under Rule 4:46-2. The court may deny a summary judgment motion without prejudice where the movant fails to file the required statement. R. 4:46-2(a). Although failure to comply with this requirement is not always grounds for denial, Hancock v. Borough of Oaklyn, 347 N.J. Super. 350, 362 (App. Div. 2002), such a determination is within the court's discretion. Because Defendants' motion is being denied without prejudice, pending a determination as to which State's law is applicable to Plaintiffs' substantive claims and claims for compensatory damages, the court requests that the parties provide statements of undisputed facts and counter-statement of facts in accordance with R. 4:46-2 for any future dispositive motions.

Jessica R. Mayer, J.S.C.